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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,211	06/02/2006	Ick-Dong Yoo	58049-00030	3530
35736 JHK LAW	7590 04/15/200	8	EXAMINER	
P.O. BOX 1078			BLAKELY III, NELSON CLARENCE	
LA CANADA	, CA 91012-1078		ART UNIT	PAPER NUMBER
			4131	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# YOO ET AL. 10/596,211

Application No.

Applicant(s)

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Office Action Summary	Examiner	Art Unit				
	NELSON C. BLAKELY III	4131				
The MAILING DATE of this communication app	pears on the cover sheet with the o	correspondence a	ddress			
Period for Repty  A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTH'S from the mailing date of the scommunication.  - If NO period for reply is specified above, the maximum statutory period.  - Failure to reply within the set or extended period for reply will. by statute Any reply received by the Cffice later than three months after the main; earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirt will apply and will expire SIX (6) MONTHS from 1, cause the application to become ABANDONE	N. nely filed the mailing date of this of D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on						
2a) This action is <b>FINAL</b> . 2b) This	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-6 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-6</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	er.					
10)⊠ The drawing(s) filed on <u>02 June 2006</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correct	tion is required if the drawing(s) is ob	jected to. See 37 C	FR 1.121(d).			
11) The oath or declaration is objected to by the Ex	caminer. Note the attached Office	Action or form P	TO-152.			
Priority under 35 U.S.C. § 119						
	priority under 35 H.S.C. & 119/a	L(d) or (f)				
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:						
1.☐ Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No.  .						
Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau	u (PCT Rule 17.2(a)).		•			
* See the attached detailed Office action for a list	of the certified copies not receive	ed.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D.  5) Notice of Informal F					
3) X Information Disclosure Statement(s) (FTO/S5/08)	6) Other:	unon Application				

Paper No(s)/Mail Date 06/02/2006.

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#### DETAILED ACTION

#### Application Status

Claims 1-6 of the instant application are pending. Claims 1-6 are under examination.

### Objections

#### Specifications

The disclosure is objected to because of the following informalities:

 The use of the trademark SEPHADEX-LH20® has been noted on page 10 of the instant specification. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

On page 2, line 13, it appears that the word "dihydorxy-phenylalanine" is meant to be "dihydroxy-phenylalanine".

Appropriate correction is required.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that *Penicillium* sp strain KCTC 26245 is required to practice the claimed invention. As such the biological material must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the *Penicillium* sp strain KCTC 26245.

The process disclosed in the specification does not appear to be repeatable, it is not clear that the invention will work with commonly available material and it is not apparent if the biological materials considered necessary to make and use the invention is both known and readily available to the public. A person skilled in the art could not make or use the invention defined in and commensurate with the claims without access to the specific biological material. It is noted that Applicant has deposited biological material but there no indication in the specification as to public availability. Therefore, a deposit at a recognized depository may be made to overcome this rejection.

If the deposit is made under the terms of the <u>Budapest Treaty</u>, then a statement, affidavit or declaration by Applicant, or by an attorney of record over his or her signature and registration number, or by someone in a position to corroborate the facts of the deposit, that the instant invention will be irrevocably and without restriction released to

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the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is a non-<u>Budapest Treaty</u> deposit, then in order to certify that the deposit meets the criteria set forth in 37 CFR §1.801-1.809 and MPEP §2402-2411.05, a statement, affidavit or declaration by Applicant, by an attorney of record over his or her signature and registration number, or by someone in a position to corroborate the facts of the deposit would satisfy the requirements herein by stating and providing that:

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) provide evidence of the test of the viability of the biological material at the time of deposit (see 37 CFR \$1.807);
  - (e) stating that the deposit will be replaced if it should ever become inviable; and
- (f) the specification must state a date of deposit, deposit number, name and address of the depository, and a taxonomic description of the deposit.

It is noted that on page 9 of the instant specification, Applicant has satisfied most of the required components of (f); however, Applicant failed to provide the address of

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the depository. Applicant is required to provide the address of the depository as specified by MPEP \$1.805(b).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The inventive compound appears to be the compound of Formula 1 defined in the instant specification; however, the formula of claim 1 does not, in fact, correspond to the compound of the invention as disclosed. Accordingly, on page 7, line 1 of the instant application, there is a double bond in the R-group at position 1 of the cyclopentene, i.e. –CH=CH-CH<sub>3</sub>, but the formula in claim 1 appears to be missing the double bond (=), i.e. –CH<sub>2</sub>-CH<sub>2</sub>-CH<sub>3</sub>. Examiner will interpret claim 1 as containing an apparent typographical error (i.e. the omission of the double bond) and, for the purposes of compact prosecution, will examine the claim as it reads upon the compound as claimed with the double bond in the R-group at position 1 of the cyclopentene.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase, "compound represented by the following formula 1 as an effective ingredient" concludes with a period, therefore, omitting Formula 1 from the metes and bounds of the claimed subject matter. For this

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reason, the claim fails to specify what is, in fact, Formula 1, and is therefore indefinite.

For examination purposes, Examiner interprets the claim to include the formula recited below claim 1.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the trademark SEPHADEX-LH20® has been noted in instant claim 6. According to MPEP §2173.05(u):

If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

Therefore, claim 6 is properly rejected under the second paragraph of 35 U.S.C. 112.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

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Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamata et al (Agricultural and Biological Chemistry, Vol. 47, Issue 11, pp. 2637-2638, 1983; cited by Applicant).

Instant claim 1 recites a melanin biosynthesis inhibitor containing terrein compound represented by Formula 1, which is anticipated by Kamata et al, figure 1, compound III. It is duly noted that claims 2-4 are directed to the intended use of the product (the inhibitor as set forth in independent claim 1); however, Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Though Kamata et al does not specifically teach the terrein compound as being a melanin biosynthesis inhibitor or the intended uses as recited in claims 2-4, the instant compound, and that which is disclosed in the reference are physically, structurally, and materially synonymous, and therefore, must actually be capable of performing the intended use as claimed. While instant claim 1 also refers to terrein as "an effective ingredient", Kamata et al discloses terrein as being a plant growth inhibitor, which anticipates the limitation of terrein as "an effective ingredient" if it is useful in the function of inhibiting plant growth.

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#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is (571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. C. B. III/ Examiner, Art Unit 4131

/Ardin Marschel/ Supervisory Patent Examiner, Art Unit 1614 Art Unit: 1614